Adora Clark
Federal Fungicide Team Lead
Syngenta Regulatory Affairs
(336) 632-7477 (Telephone)
(336) 632-5688 (Fax)
adora.clark@syngenta.com

Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

E-SUBMISSION

June 27, 2017

Document Processing Desk **(DCI/PRD)**
Attn: Linsey Walsh
Docket: EPA-HQ-OPP-2015-0459
Office of Pesticide Programs
U.S. Environmental Protection Agency **(7508P)**
One Potomac Yard, South Building
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Ms. Linsey Walsh, Chemical Review Manager, Pesticide Re-Evaluation Division

SUBJECT: Propiconazole Registration Review
Data Call-In for Propiconazole
Chemical Number 3125
GDCI-122101-1705

Dear Ms. Walsh,

On April 12, 2017 Syngenta Crop Protection, LLC received the EPA's Generic Data Call-In notice for the active ingredient propiconazole, which is undergoing registration review (EPA-HQ-OPP-2015-0459). The current Confidential Statement of Formula documents to support propiconazole technical and its end use products are on file at the EPA. As required by this data call-in, Syngenta is indicating in this letter and on the attached Data Call-In response forms, how we intend to comply with the listed data requirements.

Syngenta is agreeing to conduct and submit all of the studies listed on the "Requirements Status and Registrant's Response Form" by the specified due date with the following comments and/or exceptions:

DCI Requirements

1) **Antimicrobial Use Requirements: GLNs 875.1700, 875.2700, 835.1110, 835.3110, 835.3220, 835.3240, 835.3280, 850.3300, SS850.1000**

   Syngenta does not have any antimicrobial uses, as pointed out during the previous open docket comment period. As such, these guideline requirements do not apply to Syngenta, and will not be conducted.

2) **Foliar dislodgeable residue dissipation GLN 875.2100**

   Syngenta received an EPA HED memorandum (DP Barcode: D439690) dated April 26, 2017 to waive the turf transferable residue (TTR) data as was previously required by the propiconazole scoping document. Therefore, this DCI item is no longer required by EPA and will not be conducted.

3) **Fish acute toxicity test, freshwater and marine GLN 850.1075 and Fish early-life stage toxicity test GLN 850.1400**

EPA notes in the DCI that GLN 850.1400 may be waived if an acceptable 850.1075, freshwater fish acute toxicity study with fathead minnow is submitted. As such, Syngenta agrees to conduct GLN 850.1075 with a fathead minnow so EPA can calculate an acute to chronic ratio (ACR) using data from the freshwater fish acute toxicity study (GLN 850.1075). Therefore, Syngenta will not need to conduct the fish early-life stage toxicity test.

4) **Avian acute oral toxicity test GLN 850.2100**

Syngenta agrees to conduct an avian acute oral toxicity study using a passerine species to fulfill this data guideline requirement. The protocol for this study is being finalized and, as recommended by the DCI, will be submitted for EPA review prior to study initiation.

5) **Avian reproduction test GLN 850.2300**

Syngenta submitted a waiver request (MRID No. 50181301) to EPA on February 8, 2017 for Agency review and believes the current mallard study is upgradeable to provide sufficient information for risk assessment purposes.

6) **Pollinator Higher Tier studies (Field testing for pollinators GLN 850.3040, Residues in Pollen and Nectar/Field Residue Analysis SS-1155, and Semi-field testing for pollinators (tunnel or colony feeding studies) SS-1319)**

The need for Tier 2 and/or Tier 3 pollinator testing will be based upon the results of Tier 1 laboratory tests per EFED guidance. If EPA deems higher tier studies are needed, after their review of the Tier 1 studies, then Syngenta will conduct the studies at that time.

7) **Honey bee adult acute oral toxicity SS-1311**

Syngenta is submitting, with this 90 day response, an existing honey bee adult acute contact and oral toxicity study that meets the data requirements of this guideline.

8) **Honey bee larvae acute oral toxicity SS-1312**

Syngenta is submitting, with this 90 day response, an existing honey bee larval 8-day repeat dose study with the solo formulation end use product for consideration in meeting the data requirements of this guideline. In addition, Syngenta is submitting a formal waiver request for the honey bee larvae acute oral study with TGAI to allow the use of the formulation study.

9) **Honey bee adult chronic oral toxicity SS-1313**

Syngenta is submitting, with this 90 day response, an existing honey bee adult 10-day feeding study with the solo formulation end use product for consideration in meeting the data requirements of this guideline. In addition, Syngenta is submitting a formal waiver request for the honey bee adult chronic oral study with TGAI to allow the use of the formulation study.

10) **Honey bee larvae chronic oral toxicity SS-1314**

Syngenta agrees to conduct a honey bee larvae chronic oral toxicity study to fulfill this data guideline requirement. As recommended by the DCI, the protocol for this study is enclosed with this 90 day response, intended for EPA review prior to study initiation.

Please do not hesitate to contact me at (336) 632-7477 or by email at adora.clark@syngenta.com if there are any questions about Syngenta's response to this Data Call-In or need additional information. Also, you may contact my regulatory assistant, Stephanie, at 336-632-5970 or by email at stephanie.cole@syngenta.com

Sincerely,

Adora Clark

Adora Clark
Federal Team Lead, Fungicides
Regulatory Affairs
Syngenta Crop Protection, LLC

cc: Avivah Jakob, Team Leader, Risk Management and Implementation Branch 3

Attachments:

- Requirements Status & Registrant's Response Form with the Data Call-In Response Form
- GLN SS-1311: The Acute Contact and Oral Toxicity to Honey Bee of technical Propiconazole (Syngenta Document No. TK0325790)
- GLN SS-1312: Propiconazole EC (A6097AF) – Chronic Larval Toxicity Test on the Honey bee (*Apis Mellifera* L.) in the Laboratory (Syngenta Document No. TK0221651)
- GLN SS-1313: Propiconazole EC (A6097AF) – Assessment of Chronic Effects to the Honeybee, *Apis mellifera* L., in a 10 Day Continuous Laboratory Feeding Test (Syngenta Document No. TK0123562)
- Waiver Request to conduct the honey bee larval acute oral toxicity study with the TGAI - formulation study enclosed fulfills the SS-1312 data requirement (Syngenta Document No. TK0325789)
- Waiver Request to conduct the honey bee adult chronic oral toxicity study with the TGAI - formulation study enclosed fulfills the SS-1313 data requirement (Syngenta Document No. TK0325788
- Protocol for GLN SS-1314: Honey bee (*Apis mellifera* L.) 22 Day Larval Toxicity Test (Repeated Exposure) (Syngenta Document No. TK0317885)